

REMARKS

Interview Summary

A summary of the telephonic interview that took place on July 25, 2006 will be filed about concurrently with this response.

35 U.S.C. § 112, second paragraph

Claims 1-9 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Particularly, the rejection indicates that the phrase “substantially the same” in claim 1 renders the claim and its dependents indefinite.

Applicants respectfully disagree that claim 1 and its dependents are indefinite. As noted in MPEP 2173.05(b), reproduced below for the Examiner’s convenience, the fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. MPEP 2173.05(b) goes on to discuss the term “substantially.”

*D. “Substantially”*

The term “substantially” is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation “to substantially increase the efficiency of the compound as a copper extractant” was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation “which produces substantially equal E and H plane illumination patterns” was definite because one of ordinary skill in the art would know what was meant by “substantially equal.” *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

Accordingly, contrary to the assertion of the Examiner, the specification does not need to recite a limiting definition of the metes and bounds of “substantially the same.” Rather, the general guidelines found in the specification would apprise one of skill in the art of the metes and bounds

of the claim. *See, inter alia*, paragraph [00012] and [00039] of the present application.

Withdrawal of the rejection is respectfully requested.

Claims 7-8

Claims 7 and 8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Branton et al. (WO 00/079257).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreover, the identical invention must be shown in as complete detail as contained in the claim. *Richardson v. Suzuki Motor Co.* 868 F.2d 1226, 1236, 9USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully assert that the rejection of claim 7 is improper.

Regarding claim 7, the rejection indicates that [p]olymerases are proteins, which comprise chemical functional groups.” Applicants respectfully challenge this assertion on several grounds.

First, it appears that the Examiner is asserting that proteins in general have functional groups. Whether or not this is true, the identical invention must be shown in as complete detail as contained in the claim. *Richardson, supra*. Accordingly, it is improper to rely on characteristics of proteins in general, where Branton only discloses a subspecies thereof. To do otherwise violates the rule of *Richardson, supra*.

Second, even assuming arguendo that the Examiner relies on Branton’s polymerases to show functional groups, no showing has been made that the polymerases disclosed in Branton have functional groups. Accordingly, it appears that the rejection is unsupported.

Third, any assertion that Branton’s polymerases contain functional groups would have to rely on official notice, as no evidence has been presented to show that the proteins disclosed in Branton have functional groups. However, official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-

known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be “capable of such instant and unquestionable demonstration as to defy dispute” (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). It is never appropriate to rely solely on “common knowledge” in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697.

Applicants respectfully challenge any proposed or actual taking of official notice, and respectfully asserts that it was not notorious and well known in the art of detection of chemical and biological materials at the time of invention to use proteins containing functional groups around an aperture as suggested by the Examiner, much less the specific proteins disclosed by Branton. No showing has been made that the proteins disclosed in Branton contain functional groups.

If a future rejection of claim 7 relies on Official Notice, Applicants request a specific showing in the art that Branton’s specific polymerase contains functional groups, and that meets all of the *Graham* criteria, and further that predates Applicant’s date of invention.

For any of the foregoing reasons, the rejection of claim 1 is improper.

Claim 8 depends from claim 7, and therefore incorporates the limitations of claim 7. By virtue of its dependence, claims 3, 5 and 14 are also believed to be allowable.

#### Claims 1-5

Claims 1-5 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Branton in view of Hoger (J. Polymer Sci. Part A; Poly. Chem., vol. 37, pp.2685-2698 (1999)).

Applicants first assert that use of Hoger is improper, because Hoger is nonanalogous art. One of the first inquiries in an obviousness analysis is whether all of the references relied on are analogous art. “In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Hoger is simply a chemistry paper describing cyclic molecules. This is certainly outside the field of applicant's endeavor, that of detecting chemical or biological materials. Nor can it be said that Hoger is reasonably pertinent to the particular problem with which the inventor was concerned, namely detecting chemical or biological materials. Not only does Day not disclose detection of chemical or biological materials, no mention of detection of chemical or biological materials is provided therein. Accordingly, the rejection of claims 1-5 violates the rule of *In re Oetiker, supra*, and must be withdrawn.

Applicants next assert that the rejection is improper as failing the *Graham* test. The analysis of obviousness was set forth in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In order to establish a *prima facie* case of obviousness, three basic criteria must be met:

First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of the references. Second, there must be a *reasonable expectation of success*. Finally, the prior art reference or combined references must teach or suggest *all the claim limitations*. *The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art*, and not based on applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991; *emphasis added*).

Applicants respectfully traverse the rejection as failing the *Graham* test. Specifically, the combination proposed in the rejection fails at least the first element of the *Graham* test.

First, the claimed invention would not have been predictable from the bare teachings of the prior art itself, or in knowledge generally known to those skilled in the art. The United States Supreme Court has acknowledged that there is no obviousness where the end result is unpredictable. In the recent case, *KSR International v. Teleflex Inc.*, 550 U.S. \_\_\_ (2007), the Court's analysis included by implication the traditional notion that evidence of unpredictable results is evidence of non-obviousness. Therefore, even though the Court made sweeping changes to the obviousness analysis, it acknowledged that a showing of unpredictable results could defeat an assertion of obviousness.

The courts have repeatedly stated that the chemical arts are, by their very nature, unpredictable. This case is no different. In the instant rejection, the Examiner proposes replacing Branton's polymerase with a cyclic molecule from Hoger. However, no showing has been made that such a substitution would work, and allow Branton's device to continue to operate. Rather, any result of such a substitution is truly unpredictable. For instance, will Branton's crosslinkers couple to Hoger's cyclical molecule? If so, what will the effect be on the resultant diameter of the cyclical molecule? Will it still allow passage of Branton's single strand of DNA? Further, would Branton's invention even work after such a substitution? (Note Branton's reliance on the "biological motor" created by polymerase and DNA at p. 36, line 23 to p. 38, line 30.)

The lack of any description of using cyclicals in Branton is further evidence that such a substitution was not predictable to those skilled in the art.

Because the result of the substitution proffered in the rejection is unpredictable, the claimed invention is not obvious. Accordingly, the rejection is erroneous.

Expanding on the point above, even assuming *arguendo* that substitution of Branton's polymerase with Hoger's cyclic molecule would somehow render predictable results, such results would appear to result in rendering Branton's device inoperable, and thus unsatisfactory for its intended purpose.

Applicants therefore respectfully traverse the rejection of claim 1 as being improper, as the proposed modification would render Branton's invention unsatisfactory for its intended purpose. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Particularly, the purpose of Branton's system is to analyze portions of a DNA strand as it moves through a hole. However, if Hoger's cyclical molecule were added as suggested by the Examiner, the DNA strand would couple with the cyclical and stop. Therefore, Branton's device would no longer be able to analyze the strand in the hole, or any other strand in the sample. Accordingly Branton's device would be rendered inoperable, in violation of *In re Gordon, supra*.

Accordingly, the rejection is improper for this reason as well.

Further, the rejection proposed would require an impermissible change in the principle of operation of Branton. Particularly, Branton relies on the “biological motor” created by polymerase and DNA to pull the DNA through the hole. To remove the polymerase and replace it with Hoger’s cyclical would cause the DNA strand to bind up in the hole rather than be drawn through it, thereby defeating the principle of operation of Branton’s critical biological motor. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Accordingly, the rejection is improper for this reason as well.

For any of the foregoing reasons, reconsideration and allowance of claim 1 is respectfully requested.

Claims 2-5 depend from claim 1, and therefore incorporate the limitations of claim 1. By virtue of their dependence, claims 2-5 are also believed to be allowable. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claims 2-5 is respectfully requested.

#### Claim 6

Claim 6 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Branton in view of Hoger in yet further view of Go (US5104820).

The rejection of claim 6 applies Branton and Hoger as for claim 1. Claim 6 depends from claim 1, and therefore the rejection suffers from the same deficiencies as set forth above with respect to claim 1. Because Go has merely been added to allegedly show the limitation of the dependent claim, claim 6 is believed to be allowable over the combination proposed by the Examiner. Reconsideration and allowance of claim 6 is respectfully requested.

Claims 7 and 9

Claims 7 and 9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Branton in view of Go.

The rejection of claims 7 and 9 applies Branton as for claim 7, and therefore is erroneous for the same reasons as set forth above, namely that the rejection based on Branton is unsupported and/or improperly relies on official notice.

Reconsideration and allowance of claims 7 and 9 is respectfully requested.

New Claims

New claims 12-18 have been added to further define and vary the scope of the present invention. The claims are fully supported in the present application and drawings as originally filed. No new matter has been added.

Allowance of claims 12-18 is respectfully requested.

Conclusion

In the event that the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, he or she is respectfully requested to initiate the same with the undersigned at (925) 422-7073.

Respectfully submitted,

By: /John H. Lee#53193/      Date: January 24, 2008

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